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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,233	10/24/2003	Zehra Kaymakcalan	BBC-193	1420

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EXAMINER	
OUSPENSKI, ILIA I	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,233	KAYMAKCALAN ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Ilia Ouspenski, Group Art Unit 1644, Technology Center 1600.

2. Claims 1 – 31 are pending.

3. Applicant's election without traverse of Group I, claims 1 – 31, drawn to a method of treating a disorder with an anti-TNFα antibody, in the reply filed on 11/12/2004 is acknowledged. Applicant further elects the species of autoimmune disorders and further a species of rheumatoid arthritis.

Claims 1 – 31, as they read on a method for treating rheumatoid arthritis by administering anti-TNFα antibodies, are under consideration in the instant application.

4. The priority of the instant application is limited to reliance upon USSN 60/421,262. The provisional application USSN 60/421,262 upon which priority is claimed appears to provide adequate support under 35 U.S.C. 112 for subject matter claimed in the instant application.

When there are benefit claims to multiple prior nonprovisional applications (e.g., a string of prior nonprovisional applications), the relationship must include an identification of each nonprovisional application as either a continuation, divisional, or continuation-in-part application of a specific prior nonprovisional application for which a benefit is claimed. See United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003).

The disclosure that USSNs are "related" to one another is not a proper claim for priority.

The benefit claim filed on 10/24/2003 was not entered because the required reference was not timely filed within the time period set forth in 37 CFR 1.78(a)(2) or (a)(5). If the application is an application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a nonprovisional application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the reference to the prior application must be made during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). If applicant desires priority under 35 U.S.C. 119(e) or 120 based upon a previously filed application, applicant must file a petition for an unintentionally delayed benefit claim under 37 CFR 1.78(a)(3) or (a)(6). The petition must be accompanied by: (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted); (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

5. Applicant's IDS, filed 01/18/2005, is acknowledged. However, the references were not available to the Examiner at the time of mailing of this Office Action. The IDS will be considered in the subsequent Office Action.

6. The use of trademarks has been noted in this application (e.g. Taxotere, etc. on page 24). Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

7. The disclosure is objected to because of the following informalities: an apparent typographical error is present at least on page 26 line 13, wherein the Greek letter alpha following "TNF" has apparently been replaced by a different symbol. Appropriate correction is required.

Furthermore, Applicant's cooperation is requested in proofreading the disclosure and correcting any other errors.

8. Claims 4 – 7, 11 – 14, 17 – 20, 23, 25 – 27, and 30 – 31 are objected to under 37 CFR § 1.75(c) as being in improper form because a multiple dependent claim
cannot depend from any other multiple dependent claim, and
should refer to other claims in the alternative only. See MPEP § 608.01(n).

Even though these claims are in improper form, the examiner has chosen to examine the claims.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1 – 6, 8 – 13, 15 – 19, 21 – 26, and 28 – 31 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1 – 6, 8 – 13, 15 – 19, 21 – 26, and 28 – 31are indefinite in the recitation of a "low dose" therapy, because the metes and bounds of the claimed invention are unclear. Although the specification defines "low dose" on page 7, second paragraph as the amount which is "substantially lower than that originally employed," the definition is vague and indefinite, because "substantially lower" is still a relative term. Thus one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

B. Claims 6, 13, 19, and 26 contain the trademark/trade names Etanercept and Remicade. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade names are used to identify/describe TNFα inhibitors and, accordingly, the identification/description is indefinite.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1 – 4, 7 – 11, 14 – 17, 20 – 24, 27 – 29, and 31 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for a TNFα inhibitor which is an anti-TNFα antibody, does not reasonably provide enablement for the full breadth of the genus of "TNFα inhibitors." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification does not provide a sufficient enabling description of the claimed invention.

It is acknowledged that the elected invention limits the "inhibitor" to an anti-TNFα antibody. However, the following rejection is set forth with respect to the breadth of the instant claims as currently recited, which encompasses, for example, small molecules.

The specification discloses antibodies to TNFα and fusions of TNF receptor (e.g. page 7), while the instant claims encompass in their breadth any agent which inhibits signaling via TNFα.

A person of skill in the art is not enabled to make and use any agent which modulates signaling via TNFα commensurate with the scope of the claims as presently recited, because it was well known in the art at the time the invention was made that

molecules having highly diverse structural and biochemical properties can modulate signaling. For example, Huang (Pharmacol. Ther., 2000, 86: 201-215., see entire document) reviews e.g. on page 202 the daunting task faced by the skilled artisan in developing small molecule regulators of protein function, and notes that the process requires long periods of trial and error testing. The structure of such molecules cannot be readily envisioned by one of skill in the art based upon the guidance provided in the instant specification as-filed. Therefore, Applicant does not provide a sufficiently enabling disclosure regarding how to make and use inhibitors of TNFα, other than antibodies to TNFα.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the structural features of "agents" are unpredictable; thus the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 18 24 (CCPA 1970). "It is not sufficient to define the recombinant molecule by its principal biological activity, e.g. having protein A activity, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property." Colbert v. Lofdahl, 21 USPQ2d, 1068, 1071 (BPAI 1992).

13. Claims1 – 4, 7 – 11, 14 – 17, 20 – 24, 27 – 29, and 31 are rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

Applicant is not in possession of a method for treating a disorder by administering a TNFα inhibitor.

It is acknowledged that the elected invention limits the "inhibitor" to an anti-TNFα antibody. However, the following rejection is set forth with respect to the breadth of the instant claims as currently recited, which encompasses, for example, small molecules.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. (See Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column). A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. MPEP 2163 II.A.3a.ii.

The claims recite a method utilizing TNFα inhibitor. However, the specification does not appear to provide a sufficient number of representative species to support a genus of "inhibitors". The specification discloses antibodies to TNFα and fusions of TNF receptor (e.g. page 7). These "inhibitors" lack a common structure essential for their function and the claims do not require any particular structure be shared by the instant "inhibitors". The genus of "inhibitors" is thus extremely large, and the specification does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not convey to a person of skill in the art that the Applicant is in possession of the genus of TNFα inhibitors, in particular small molecules, commensurate with the scope of the claims as presently recited, because it was well known in the art at the time the invention was made that molecules having highly diverse structural and biochemical properties can modulate signaling in immune cells. Huang (Pharmacol. Ther., 2000, 86: 201-215) reviews e.g. on page 202 the daunting task faced by the skilled artisan in developing small molecule agents which modulate protein function, and notes that the process requires long periods of trial and error testing. The structure of such agents cannot be readily envisioned by one of skill in the art based upon the written description provided in the specification as-filed.

Thus it does not appear based upon the limited disclosure that Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the limited number of species disclosed and the extensive variation permitted within the genus of "inhibitors", including, in particular, small molecules.

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. It is noted that the recitation of "low dose therapy" in the instant claims is vague and indefinite (see rejection under 35 U.S.C. 112, second paragraph, above); however, for examination purposes it is assumed that the low dose encompasses 0.01 – 2.0 mg/kg as recited e.g. in claim 7.

16. Claims 1 – 31 are rejected under **35 U.S.C. 102(b)** as being anticipated by Salfeld et al. (US Patent No. 6,258,562; see entire document).

Salfeld et al. teach a method of treating rheumatoid arthritis by administering anti-TNFα antibody D2E7, the same antibody as claimed in the instant application (see entire document, in particular, e.g. column 4 last paragraph in view of column 3 first paragraph). Salfeld et al. teach that the effective dose of the antibody is 0.1 – 20 mg/kg (column 26 lines 26 – 29). Salfeld et al. further teach that for treating rheumatoid arthritis, the antibody can be administered with a plurality of additional therapeutic agents (column 23 second paragraph). Since the same disorder is treated by Salfeld et al. as disclosed in the instant application, the symptoms of the disorder are inherently

the same. Therefore there is no manipulative difference between the claimed method and the method taught by the prior art.

Thus the reference teachings anticipate the claimed invention.

17. Claims 1 – 31 are rejected under **35 U.S.C. 102(e)** as being anticipated by Salfeld et al. (US Patent No. 6,509,015; see entire document).

Salfeld et al. teach and claim a method of treating rheumatoid arthritis by administering an anti-TNFα antibody, alone or in combination with additional therapeutic agents (see entire document, in particular, claims 4 – 8, 16, 17, 36 – 40, 48, 49, and 68 – 70). Salfeld et al. further teach that the antibody identified in the claims by SEQ ID NOS is the D2E7 antibody (e.g. columns 2 – 3 bridging paragraph), i.e. the same antibody as recited in the instant claims. Since the same disorder is treated by Salfeld et al. as disclosed in the instant application, the symptoms of the disorder are inherently the same.

Thus the reference teachings anticipate the claimed invention.

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1 – 31 are rejected under the judicially created doctrine of **obviousness-type double patenting** as being unpatentable over claims 1 – 100 of U.S. Patent No. 6,509,015. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons set forth herein.

It is acknowledged that the elected invention in the instant application is limited to a method or treating rheumatoid arthritis; however, certain claims of U.S. Patent No. 6,509,015 which read on other diseases are included in this rejection because they anticipate the broad instant claims as presently recited.

Claims 1 – 100 of U.S. Patent No. 6,509,015 are directed to a method of treating a disease, such as rheumatoid arthritis, by administering an anti-TNFα antibody, alone or in combination with additional therapeutic agents. The specification clarifies at columns 2 – 3, bridging paragraph, that the antibody identified in the claims by SEQ ID NOS is the D2E7 antibody, i.e. the same antibody as recited in the instant claims. Since treatment of the same disorder is claimed in U.S. Patent No. 6,509,015 as in the instant application, the symptoms of the disorder are inherently the same, and therefore are not patentably distinct from the instant claimed invention.

Claims 1 – 31 are directed to an invention not patentably distinct from claims 4 – 8, 16, 17, 36 – 40, 48, 49, and 68 – 70 of commonly assigned U.S. Patent No. 6,509,015 for reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent No. 6,509,015, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

20. Claims 1 – 31 are provisionally rejected under the judicially created doctrine of **obviousness-type double patenting** as being unpatentable over claims 47 – 56 of copending Application USSN 10/302,356. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons set forth herein.

Claims 47 – 56 of copending Application USSN 10/302,356 are directed to a method of treating rheumatoid arthritis by administering an anti-TNFα antibody, alone or in combination with additional therapeutic agents. The specification clarifies e.g. on page 3 first paragraph that the claimed methods employ antibody D2E7, i.e. the same antibody as recited in the instant claims. Since treatment of the same disorder is

claimed in copending Application USSN 10/302,356 as in the instant application, the symptoms of the disorder are inherently the same, and therefore are not patentably distinct from the instant claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 – 31 are directed to an invention not patentably distinct from claims 47 – 56 of commonly assigned Application USSN 10/302,356 for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned USSN 10/302,356, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

21. Conclusion: No claim is allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 572-273-2920.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Patent Examiner
Art Unit 1644

February 2, 2005

Phillip Gambel
PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
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2/3/05